Revenue

Revenue	YoY Change
¥ 74.0 billion	+ 3.8 %

Breakdown of Revenue

(Billion yen)

	FY 2018 Q1	FY 2019 Q1	YoY Change
Revenue of Goods and Products	53.9	**53.2**	− 1.3 %
Royalty & other revenue	17.4	**20.8**	+ 20.0 %
(Opdivo)	(13.4)	**(15.4)**	(+ 15.7 %)
Total	71.2	**74.0**	+ 3.8 %

Revenue in the first quarter of the fiscal year amounted to 74.0 billion yen, an increase of 2.7 billion yen, or 3.8%, compared with the same period of the previous fiscal year.

While sales of Orencia SC, Forxiga, Parsabiv for dialysis remained steady, revenue of goods and products decreased by 0.7 billion yen (-1.3%) to 53.2 billion yen year-on-year, due to a decline in sales of Opdivo and long-term listed products.

Royalties and other revenue increased by 3.5 billion yen (20.0%) to 20.8 billion yen year-on-year. Opdivo royalty revenue from Bristol-Myers Squibb increased by 2.0 billion yen (15.7%) to 15.4 billion yen year-on-year. Royalty revenue from Merck increased 1.4 billion yen, or 55.7%, to 4.0 billion yen.

Revenue

Sales of Major Products

(Billion yen)

	FY 2018 Q1	FY 2019 Q1	YoY Change
Opdivo	22.8	**22.3**	- 2.0 %
Glactiv	7.1	**6.9**	- 2.1 %
Orencia SC	4.3	**4.9**	+ 13.6 %
Forxiga	3.6	**4.4**	+ 22.5 %
Emend/Proemend	2.7	**2.9**	+ 8.8 %
Rivastach	2.3	**2.3**	- 2.0 %
Parsabiv	1.3	**1.7**	+ 33.2 %
Kyprolis	1.3	**1.4**	+ 3.1 %
Onoact	1.1	**1.3**	+ 13.1 %
Staybla	1.0	**0.9**	- 15.6 %

In terms of overview by product, while the use of Opdivo, antineoplastic drug, was expanded for the treatment of renal cell cancer, the Opdivo sales decreased by 0.5 billion yen (-2.0%) to 22.3 billion yen year-on-year due to the impact of the drug price revision in November last year and intensifying competition with other competitors.

Among other major products, Orencia SC for rheumatoid arthritis, increased by 0.6 billion yen (13.6%) to 4.9 billion yen. Forxiga for diabetes increased 0.8 billion yen, up 22.5% to 4.4 billion yen year-on-year.

Combined sales of Emend Capsules and Proemend for IV Injection both for chemotherapy-induced nausea and vomiting increased by 0.2 billion yen (8.8%) to 2.9 billion yen year-on-year. Sales of Parsabiv for dialysis for secondary hyperparathyroidism in patients on hemodialysis steadily increased by 0.4 billion (33.2%) to 1.7 billion yen year-on-year.

On the other hand, sales of Glactiv for type 2 diabetes declined by 0.2 billion yen (2.1%) to 6.9 billion yen year-on-year.

Sales of Rivastach for Alzheimer's disease and Kyprolis for multiple myeloma were 2.3 billion yen and 1.4 billion yen year-on-year, respectively, which remained unchanged from the same period of the previous fiscal year.

Revenue

Sales of Long-term Listed Products

(Billion yen)

	FY 2018 Q1	FY 2019 Q1	YoY Change
Opalmon	2.9	**2.3**	- 20.2 %
Recalbon	2.7	**1.4**	- 49.3 %
Onon capsule	1.1	**0.9**	- 19.5 %
Onon dry syrup	0.7	**0.6**	- 14.4 %

Sales of Opalmon and Recalbon significantly decreased due to the impact of continuous generic drug use promotion policies.

Operating Profit

Operating Profit	YoY Change
¥ 20.0 billion	+ 11.1 %

Costs, etc.

		(YoY Change)	
・Cost of sales	¥ 20.7 billion	(+ 2.9%)	
・R&D expenses	¥ 16.0 billion	(+ 1.6%)	①
・SG&A expenses	¥ 16.6 billion	(- 2.7%)	②
①+② Total	¥ 32.5 billion	(- 0.6%)	
・Other income	¥ 0.1 billion	(- 44.2%)	
・Other expenses	¥ 0.9 billion	(+ 42.1%)	

Next, operating profit increased by 2.0 billion yen, or 11.1%, year-on-year to 20.0 billion yen. Cost of sales increased 0.6 billion yen, or 2.9%, to 20.7 billion yen.

R&D expenses increased 0.3 billion yen, or 1.6%, to 16.0 billion yen, mainly due to an increase in Opdivo infusion-related expenses. SG&A expenses, excluding R&D expenses, decreased 0.5 billion yen, or 2.7%, to 16.6 billion yen, mainly due to a decrease in operating expenses.

Operating profit increased by 2.0 billion yen year-on-year due to an increase in revenue of 2.7 billion yen despite an increase in expenses.

Profit before Tax

Profit before Tax	YoY Change
¥ 21.2 billion	+ 9.1 %

Net financial income

+ ¥ 1.2 billion (- ¥ 0.2 billion)

Finance income :	**¥ 1.5 billion**
(Interest and dividend income received, etc.)	
Finance costs :	**¥ 0.3 billion**
(Interest expense arising from lease obligations and employee retirement benefit, exchange losses etc.)	

Profit before tax increased 1.8 billion yen, or 9.1%, year-on-year to 21.2 billion yen. This was due to a net decrease of 0.2 billion yen in finance income and costs to 1.2 billion yen.

Profit for the Period
(Owners of the Parent Company)

Profit for the Period (Owners of the Parent Company)	YoY Change
¥ 16.3 billion	+ 7.2 %

Income tax expense

¥ 4.8 billion (YoY Change + 15.3 %)

(Major change factors)

Increase in profit before tax	¥ 1.8 billion
Increase in corporate tax	¥ 0.6 billion

Lastly, profit for the period (owners of the parent company) increased 1.1 billion yen, or 7.2%, to 16.3 billion yen due to an increase in profit before tax. There are no revisions to the full-year consolidated earnings forecast announced on May 9.

I will explain the progress of major development pipelines and the prospects for future applications.

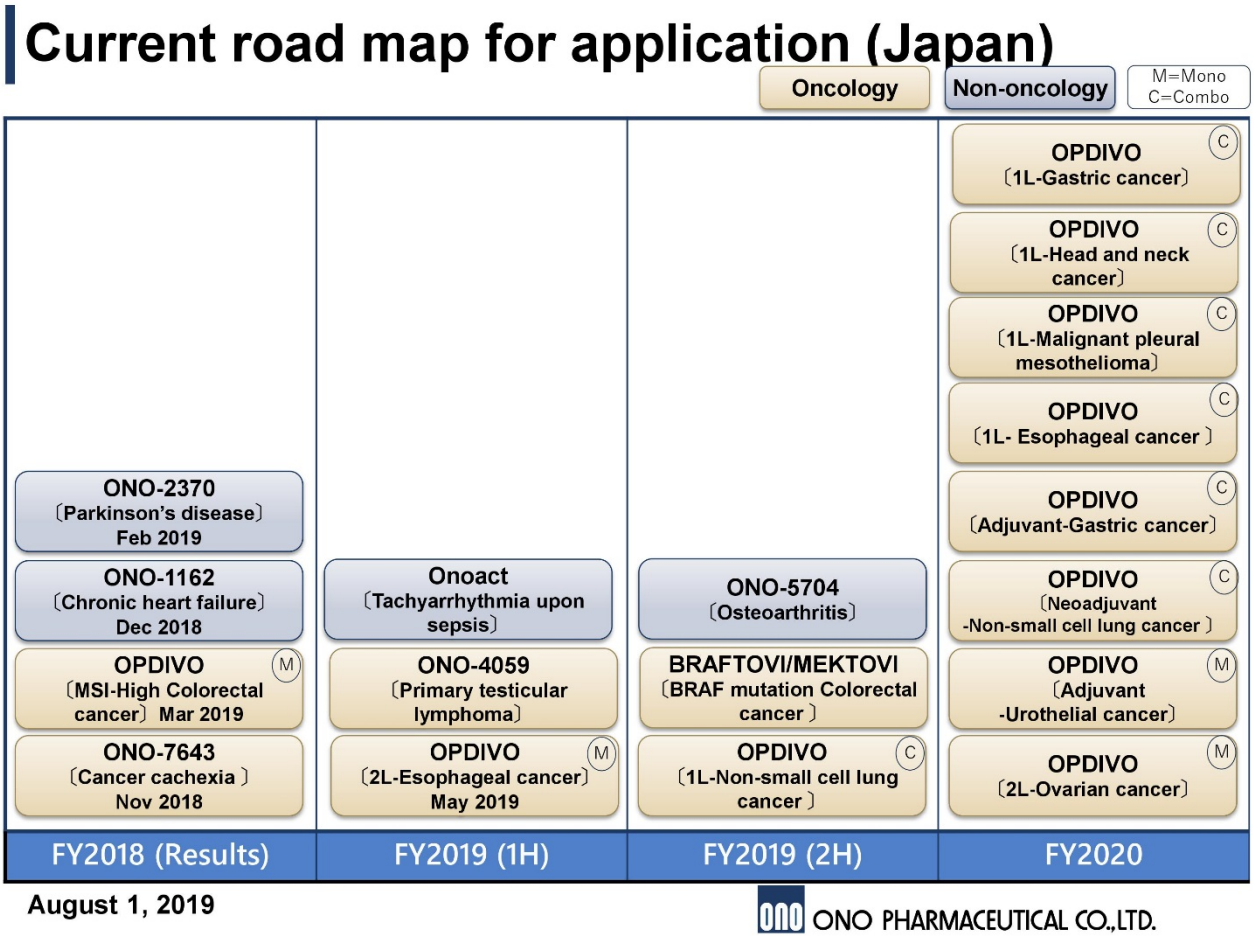
The progress of the products under development is shown on pages 13 to 23 of the financial results summary. It describes the oncology field first. In that, Japan is explained first, followed by South Korea, Taiwan, and Europe and the United States. Then, the areas outside of oncology are listed in the same order.

First, please refer to page 13. As the bottom of the middle table shows, we have filed for esophageal cancer in May of this year.

On page 17, Opdivo monotherapy was approved in Taiwan for microsatellite instability high or DNA mismatch repair deficiency colorectal cancer. In addition, we have also received approval for a combination therapy that uses both Opdivo and Yervoy in the same filing.

Next, the bottom row of page 22 shows that the ONO-4685 has now entered Phase 1 at this time. ONO-4685 is a bispecific antibody that targets both an active T-cell-induced PD-1 molecule and a T-cell distinctively expressing CD3 molecule. We have begun Phase 1, which we consider to be a target for autoimmune diseases.

Please turn to page 16. We have discontinued the development of an ID01 inhibitor (ONO-7701) and an anti-CD137 antibody (ONO-4481) for strategic reasons.



We included the scheduled application in Japan on page 19, the final page, of the briefing material of the financial results used in the announcement in May 2019. I'll update the information.

As I mentioned earlier in the briefing on our financial results, we applied for Opdivo for esophageal cancer in May this year.

Regarding the application for the 1L treatment of gastric cancer, we planned to submit an application in the first half of FY2019. However, as we are waiting for the OS at the primary endpoint, we have revised the application schedule to FY2020.

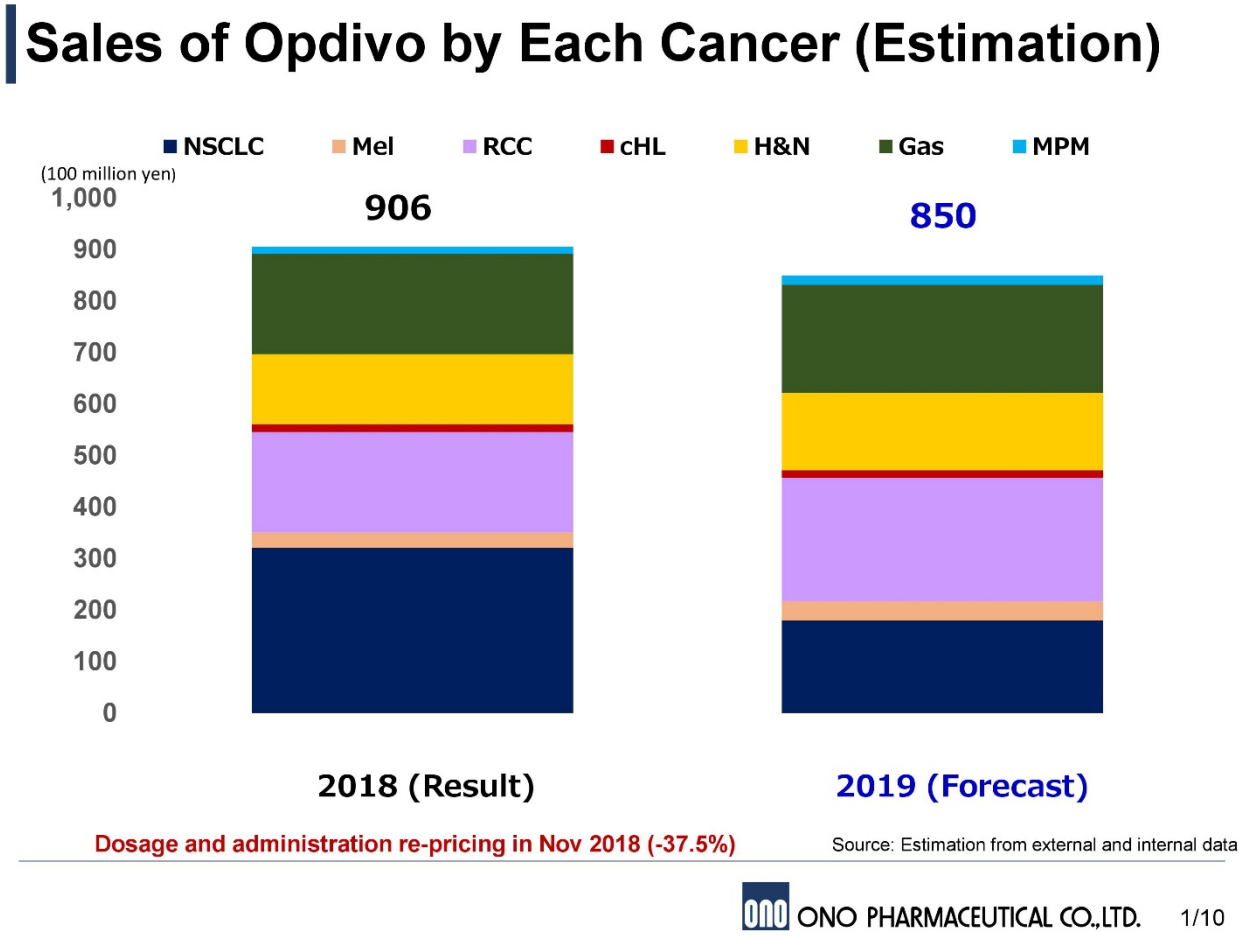
Regarding the 1L treatment for hepatocellular cancer, the application was scheduled for the second half of FY2019, but the expected results were not obtained. We will exclude this from this sheet.

The results of CheckMate-227 trials for the 1L treatment of non-small cell lung cancer came out. With the use of Ipilimumab and Opdivo in combination with PD-L1 of 1% or more, we achieved the primary endpoint OS. As planned, we are preparing to file an application in the second half of FY2019.

On the other hand, the primary endpoint OS has not been achieved for the combination therapy with chemotherapy.

Next is the 1L treatment for head and neck cancer. Phase 3 has been implemented in combination with Ipilimumab. Based on the planned achievement of the event, the application schedule was changed from the second half of FY2019 to FY2020.

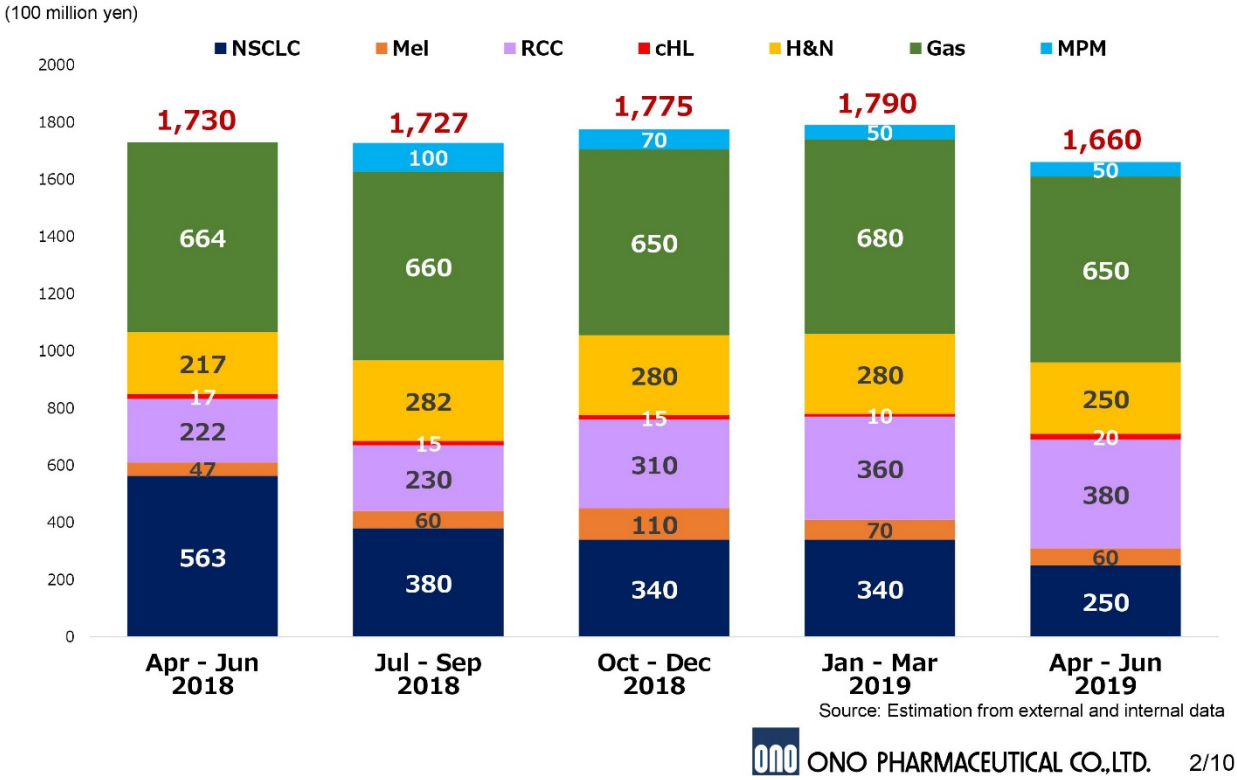
Today, I would like to report the general situation, non-small cell lung cancer, gastric cancer, and renal cell cancer.



I would like to introduce Opdivo sales. From the bar graph on the left, the results for FY2018 and the forecast for FY2019 are shown.

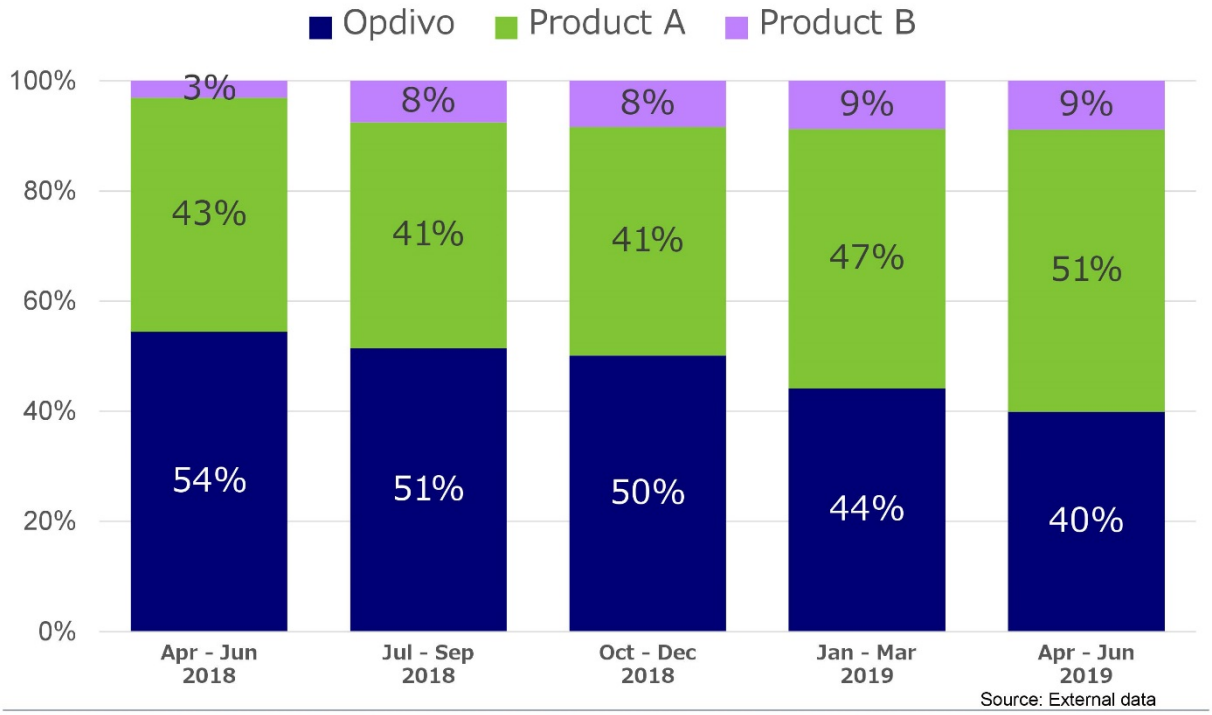
The FY2018 result was 90.6 billion yen and this fiscal year is expected to be 85.0 billion yen, due to the impact of the drug price revision in November of last year and the expected decline in the base of new prescriptions for lung cancer.

Number of Patients Newly Prescribed with Opdivo by Each Cancer (Estimation)



The slide shows the trends in the number of patients prescribed with Opdivo by each cancer with the monthly average number of patients divided by quarter from the left-hand bar chart, from the April-to-June quarter of FY2018 to the April-to-June quarter of FY2019. It is estimated that the number of new prescriptions received in April to June 2019 was 650 for gastric cancer and 380 for renal cell cancer, and the average number of new prescriptions received per month was 1,660. However, the number of prescriptions received for non-small cell cancer is declining in the competitive environment.

Sales Ratio of I-O Products in All Types of Cancer (Estimation)



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Sales ratio of I-O products in all types of cancer competing with Opdivo are presented on a quarterly basis from the left-hand bar chart, from April to June 2018 to April to June 2019. In April to June 2019, Opdivo accounted for 40% of the main I-O products.

Average Treatment Period of Opdivo in Each Cancer

Estimated treatment period

Average treatment period of each cancer is estimated based on Kaplan-Meier curves for PFS of each treatment line by each cancer at the clinical development stages.

Melanoma	:	5.0 months	
Lung cancer	:	4.5 months	
RCC (2nd line)	:	9.5 months	
Hodgkin lymphoma	:	18.0 months	
H&N cancer	:	4.5 months	
Gastric cancer	:	3.0 months	
MPM	:	4.3 months	
RCC (1st line)	:	9.9 months	(Not reach median value)

Average treatment period of Opdivo for lung cancer based on DPC data

Subjects： Patients who started the treatment by December 2017

Average treatment period
2nd line ： 5.0 months
3rd line ： 3.0 months

Note: As patients currently under treatment are included, it is anticipated that the period will be further prolonged as time proceeds.

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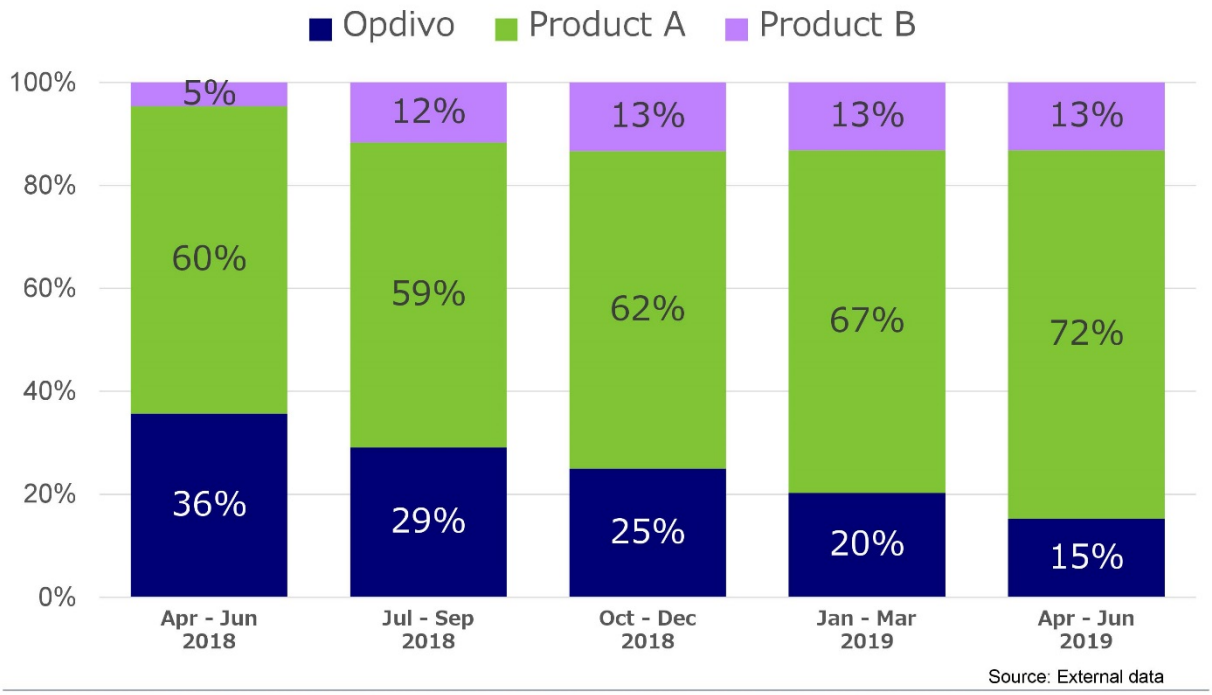
The average treatment period of Opdivo is presented by each cancer type.

The average duration of administration is estimated from the Kaplan-Meier curves of PFS by treatment line for each cancer type at the time of development trial. Depending on the type of cancer, the estimated duration of administration differs with a minimum of 3 months and a maximum of 18 months. For details, please refer to the materials on hand.

Sales Ratio of I-O Products (Estimation)

【NSCLC】



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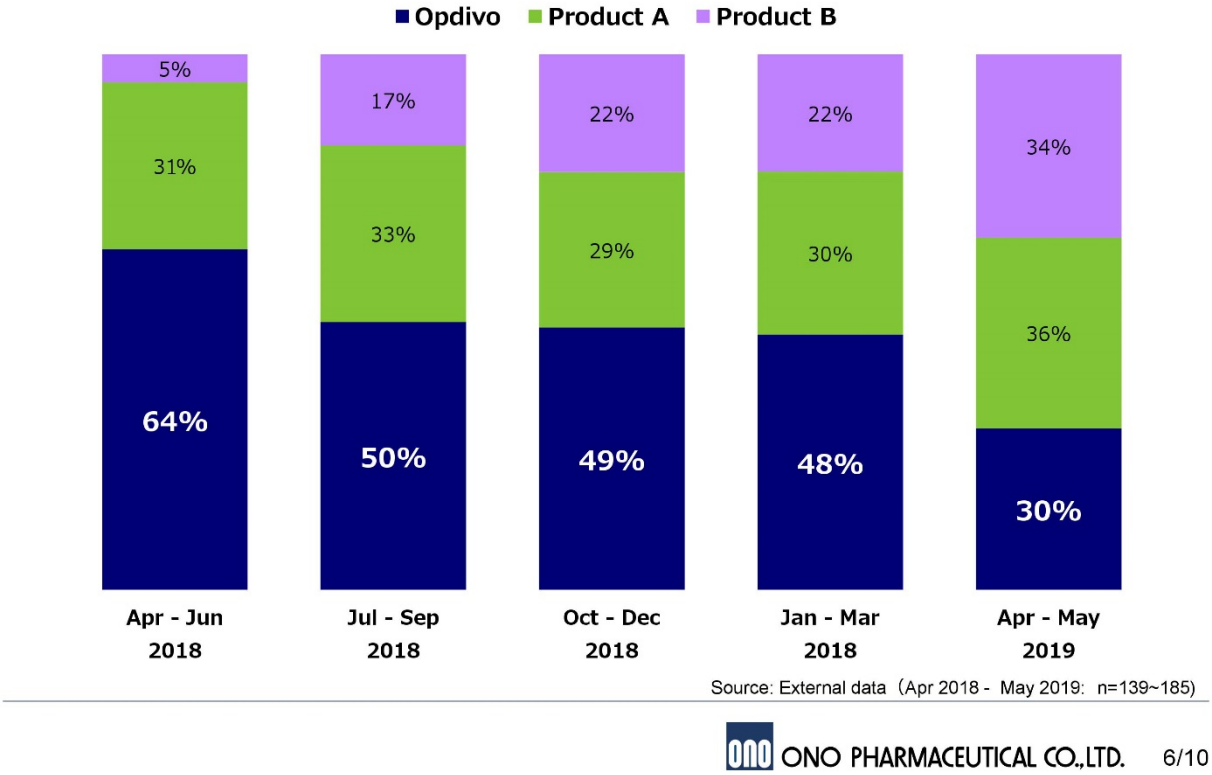
Next, I will explain the case of lung cancer.

First, the sales ratio of total non-small cell lung cancer, including 1L, 2L and 3L treatment onward, is shown on the slide. From the bar graph on the left, quarterly data from April to June 2018 to April to June 2019 are shown.

As you know, in December of last year, the combination therapy with a competitor's I-O product was approved for the 1L treatment for non-small cell lung cancer, expanding market share. In the April-to-June quarter of FY2019, Opdivo's market share was 15%, reflecting harsh market conditions.

Prescription Ratio of I-O Products Starting Treatment for 2nd Line NSCLC (Estimation)



Source: External data (Apr 2018 - May 2019: n=139~185)

Prescription ratio of I-O products for 2L treatment for non-small cell lung cancer field is presented here.

Regarding the marketability of 2L treatment, there has been a steady decline in the number of I-O products and untreated patients in 2L treatment due to the penetration of combination therapy with I-O products in 1L treatment for non-small cell lung cancer.

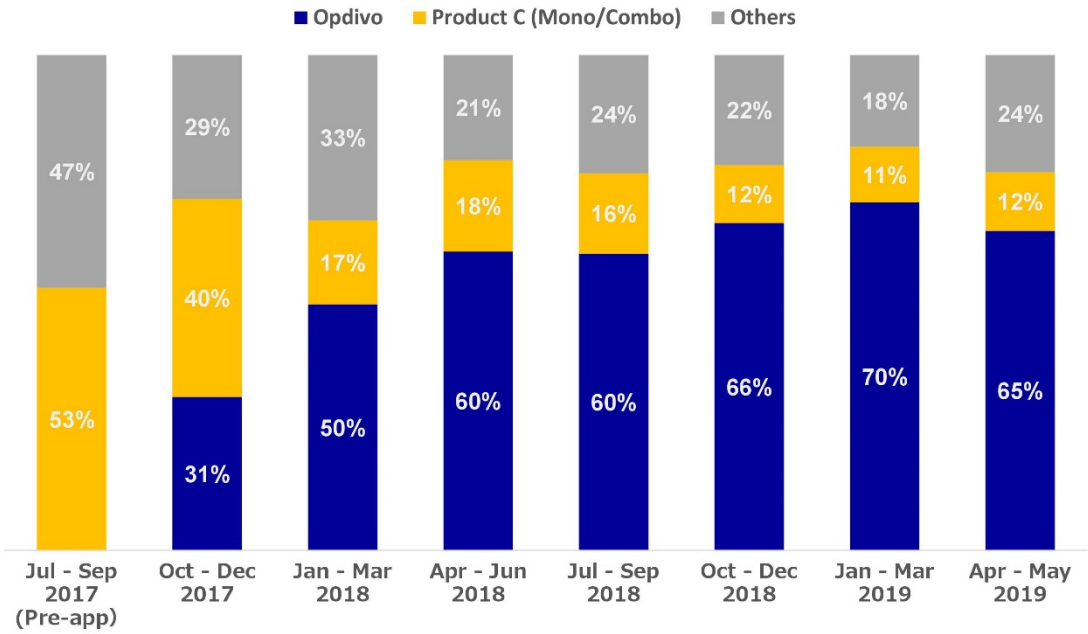
This slide shows the prescription ratio of various I-O products for 2L treatment among patients who have been newly prescribed an I-O product. From the bar graph on the left, quarterly data from April to June 2018 to April to June 2019 are shown.

As a result of intensified competition with competing drugs, the share of Opdivo prescriptions among I-O products declined 30% in April to June 2019. Despite challenging conditions, we will again emphasize the usefulness of our Opdivo, aiming to recover our market shares and achieve our sales targets.

This section explains the area of gastric cancer. Our initiatives for Opdivo in the area of gastric cancer are to position Opdivo as the first standard treatment drug in the 3L treatment of gastric cancer. Second, we are conducting activities aimed at raising awareness and promotion of the maintenance of treatment to the 3L treatment of gastric cancer.

Prescription Ratio in Patients Newly Treated for 3rd Line Gastric Cancer

※ Patients starting 3rd line treatment of gastric cancer within the last 3 months



Source: External data (Jul 2017 – Mar 2019: n=190~250)

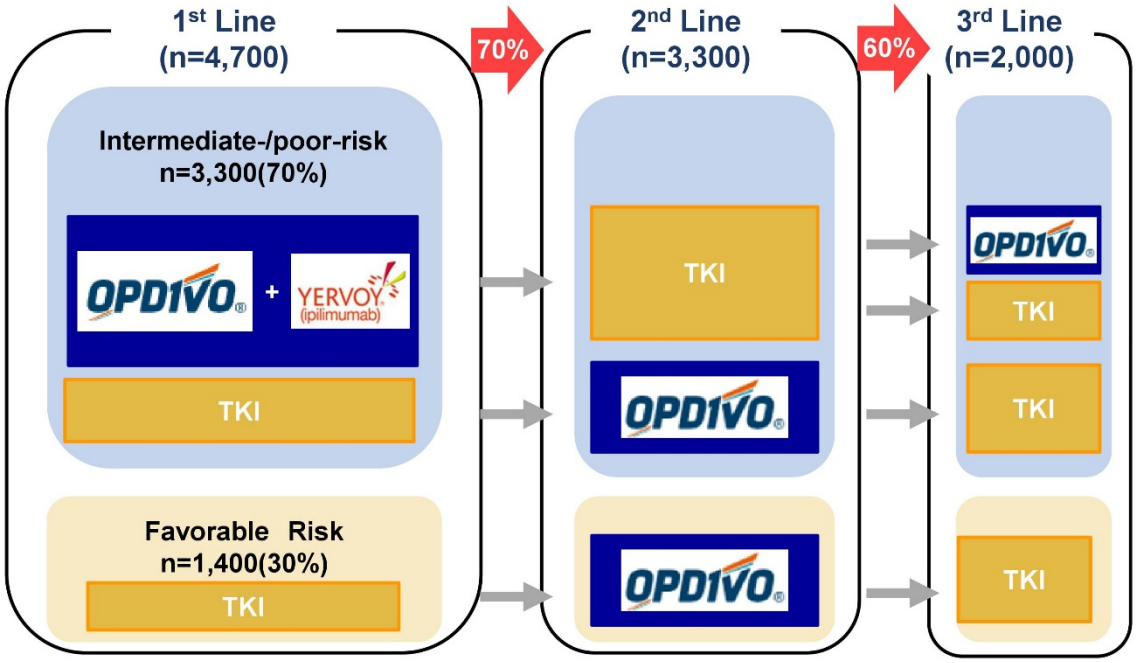
Here is the trend in the share of new patients in the 3L treatment for gastric cancer.

Since the approval of Opdivo for treatment of 3L gastric cancer in September 2017, the share of new prescriptions has been growing and recently reached 65%. We will continue to expand our position as the standard treatment drug.

Lastly, I will talk about the field of renal cell cancer.

Opdivo was approved for 2L treatment for kidney cells in 2016, and in August of last year, it was approved for the 1L treatment in combination with Yervoy.

Annual Drug-treated Patients with Advanced or Metastatic RCC in Japan



Estimation based on internal survey (2018)

This lists the number of patients with renal cell cancer subject to Opdivo. The number of patients under 1L treatment is estimated to be 4,700, 2L treatment 3,300, and 3L treatment 2,000. 3,300 patients with intermediate/poor risk, which accounts for 70% of 1L treatment patients, are subject to 1L treatment of renal cell cancer for Opdivo and Yervoy.

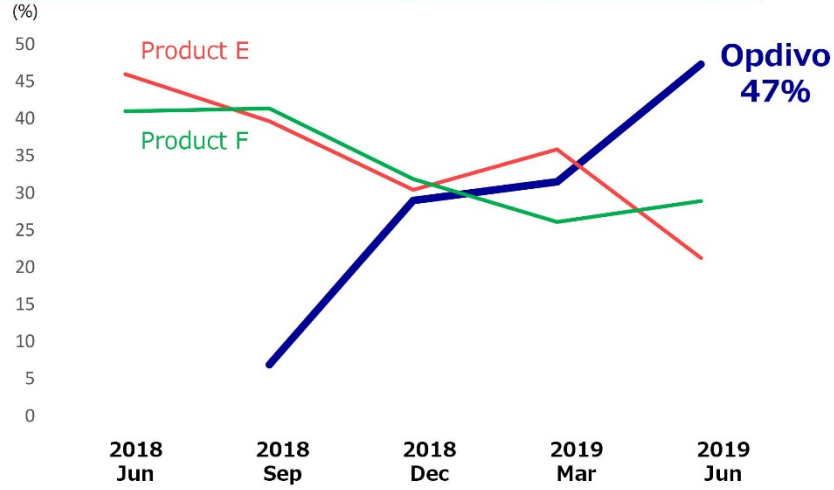
On the other hand, Opdivo alone is targeted in patients for 2L treatment or later.

As you are aware, the prognosis for metastatic renal cell cancer has improved due to the treatment with molecular target drugs. However, there is still an unmet need for intermediate/poor risk patients that the effects of these drugs cannot be sufficiently obtained.

In Japan, The Japanese Urological Association published an update on the Renal Cancer Practice Guidelines 2019 in May of this year. In the update, Opdivo and Yervoy combination therapy are recommended as Grade A for the 1L treatment in patients with intermediate/poor risk of renal cell cancer.

Prescription Ratio in Patients Newly Treated for Advanced or Metastatic 1st Line RCC

	2018 Jun	Sep	Dec	2019 Mar	Jun	
Opdivo	**-**	**7**	**29**	**32**	**47**	(%)
Product E	46	40	30	36	20	(%)
Product F	41	41	32	26	28	(%)

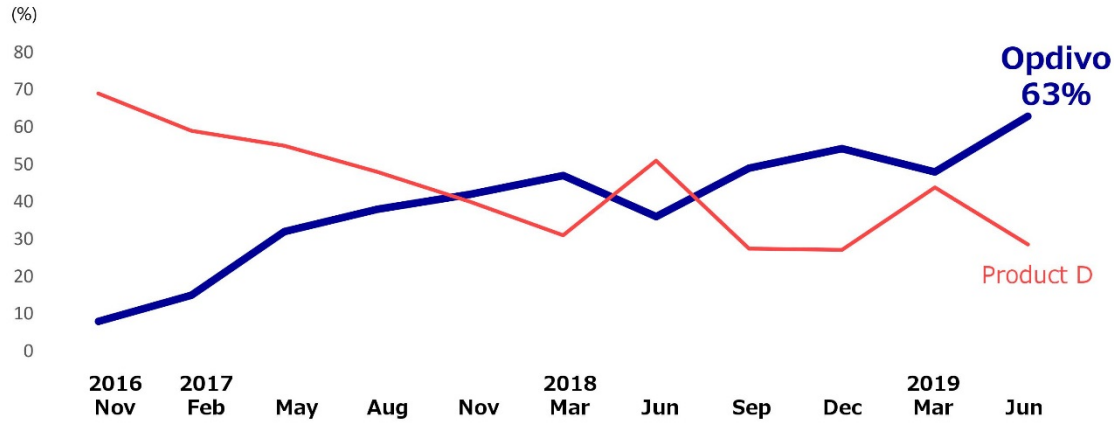


Source: External data（Sep 2018 - Jun 2019: n=39~57)

In the 1L treatment for renal cell cancer, the share of new prescriptions for Opdivo is increasing, and rising to nearly 50%. If we focus on the intermediate/poor risk areas targeted for the combination therapy of Opdivo and Yervoy, we find that the new patients account for more than 60% of the total.

Prescription Ratio in Patients Newly Treated for Advanced or Metastatic 2nd Line RCC

	2016 Nov	2017 Feb	May	Aug	Nov	2018 Mar	Jun	Sep	Dec	2019 Mar	Jun	
Opdivo	8	15	32	38	42	47	36	49	54	48	63	(%)
Product D	69	59	55	48	40	31	51	27	27	44	29	(%)



Source: External data (Nov 2016 – Jun 2019 n=32~57)

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Combination of Opdivo and Yervoy in 1L treatment has been expanding, and the number of patients who have not been treated using I-O products for 2L therapy has been decreasing gradually. In the meantime, the latest share of new prescriptions of Opdivo alone has reached 60%.

By continuing to promote both 1L and 2L treatment at the same time, we will strive to further expand prescriptions, work to deliver Opdivo treatment opportunities to patients with renal cell cancer, and increase our presence in the field of renal cell cancer.

So far, we have introduced Opdivo trends, general conditions, non-small cell lung cancer, gastric cancer, and renal cell cancer. We will continue our activities to meet the unmet needs of cancer patients.

Question & Answer

Q : I have a couple of questions, and the first one is about the performance of this first quarter. Would you briefly comment on the performance progress compared to your plan? I would like to hear strong and weak points from an overall perspective and also by item.

A : As you can see from the financial results brief report, the results were almost in line with the plan, both for consolidated and non-consolidated figures. In a sense, there was no significant growth, and there was no significant shortfall from our expectations. Although there were some ups and downs in this quarter, it was almost in line with the plan. I believe it is on the planned line, including Opdivo. That is all.

Q : The second point is about the trend in the share of new prescriptions for gastric cancer third lines on page seven showing Opdivo trend data. The Opdivo share of new prescriptions in April and May has declined slightly. Is this like a noise that lies within ups and downs in the normal course? Or are there some clear factors and, therefore, the trend is changing a little? Could you explain about why it slightly declines here?

A : Thank you for pointing that out, but we consider that just as noise. We do not believe there will be any significant changes.

The number of doctors surveyed on page seven is limited to a certain extent, so I believe this shouldn’t be applied in all aspects.

As I mentioned earlier, the market for patients with 3L treatment remains extremely large, and we would like to work to further raise this level.

Q : My last question is about the reason for the change in the filing date for the Opdivo's first line for gastric cancer. As you mentioned earlier, you were waiting for the outcome of the OS, and the primary endpoints of this trial were PFS and OS. Would you tell us about any difference between this quarter results and the forecast for the first half of this year announced at the May briefing session?

I imagine that, for example, the results of PFS were bad, so you could not submit an application using PFS alone. Or the perspective of the authorities differed somewhat from that of your company about the extent to which data is necessary before the application is submitted. This is just my guess, though.

Would you tell us why this change has occurred?

A : We will refrain from answering that question because it is related to the filing on the progress.

Q : I easily come up with various reasons, but do you think what I have just mentioned are obviously wrong in general?

A : I don't think there is a lot of thought about it in general. I think that could be possible.

Q : I appreciate you indicated the updated application timing, but if it is changed, it is naturally brought up as a question in the question-and-answer session.

The application timing of head and neck cancer was also slightly changed, wasn't it? Are there any special reasons for this?

A : We have delayed the achievement timing of the OS from the previous time as a result of updating this time.

Q : You mentioned the ChackMate-227 Part 1a worked well and the Part 2 did not work well. An application was submitted in combination with a low-volume Yervoy, but it didn't reach the required results for Part 2 in combination with chemotherapy. I think it's difficult to make a success, but how do you compete with established single-agent players or players who deals with chemo in this low-volume Yervoy plus Opdivo?

Could you tell us about your thinking in terms of initiatives in Japan?

A : As you mentioned, the Part 1a met the requirements this time. However, we are not yet looking at the actual data in more detail, and we will check that later.

We believe that in the positive cases, IO/IO's strengths in PD-L1, which met the requirements this time, are response rate and long-term survival. After the additional indication, we would like to fully promote this area and deliver it to doctors and also patients.

Q : This hasn't reached a top line, but does it in ESMO?

A : We haven't decided which academic society. It also needs to be balanced with Bristol-Myers.

Q : In addition, the gross profit margin for the entire company is slightly lower than the full-year forecast. Is this going to rise in line with the milestone from now on? A price revision is expected in the second half of the fiscal year, so I think there are negative factors in the second half of the fiscal year.

If the difference is within the range of error, it is acceptable, but it seems that the gross profit margin has started slightly lower than the full-year assumption. What about this situation?

A : The reason for the decline in the cost of sales ratio in the current fiscal year at the time of the initial announcement was that the cost of sales for ensuring stable supplies of Opdivo active pharmaceutical ingredients, which had been incurred in the previous fiscal year, will disappear in the current fiscal year.

As no such expenses were incurred in the first quarter of the previous fiscal year, it was not anticipated in the planning stage that these expenses would decrease in comparison with the first quarter alone.

Q : That was Q3, right?

A : It started to have an effect around cumulative Q3.

Q : You started seeing the effect. I understand. So, if this is included, it is within your assumption for the full fiscal year.

A : We don't think it needs to be revised at this point.

Q : You now have PD-1 by CD3 bispecific antibody as ONO-4685. My understanding is that it suppresses immune system and has an effect on autoimmunologic diseases. This is an amateur question. Does this antibody revitalize the PD-1?

A : It inhibits active T-cells, and then, it obstructs active T-cells. This is a compound that combines these two functions. Anyway, it suppresses active T-cells.

Q : Inhibiting the PD-1 causes to inhibit the other one? It seems like something opposite, but that's not true.

A : Both the PD-1 molecules and the CD3 are seen in T-cells. When PD-1 and CD3 bridge together, it makes T-cells inactive. In such a case, therefore, you should consider this to be the PD-1's agonist function. This is the opposite effect to Opdivo.

Q : So, it's going to be agonistic.

A : The other is to suppress activated T-cells by impairing T-cells by associating the CD3 of PD-1 expressing cells with other cells. We expect these two effects. Either way, they suppress immune.

Q : First, I would like you to tell us about the idea of applying for the results of CheckMate-227. Because the Part1a has succeeded this time, I think you will submit an application for the area around the PD-L1 positive this time, but I think there is a discussion about TMBs. In fact, I think there was little difference in concentration within the range of TMBs, but how do you think you are dealing with that?

Are you going to apply for PD-L1 negative in line with this PD-L1 positive application?

A : In Japan, we are not currently considering an application for TMB. Therefore, we are planning to apply for applications in areas with a PD-L1 positive rate of 1% or more.

Q : I would like to hear about the current trends of 2L treatment for non-small cell lung cancer?

The reason for the decline in the share in April and May is thought to be due to the penetration of Keytruda in the 1L treatment, so that it is no longer usable.

On the other hand, in this green area, it seems like Keytruda, but if the PD-L1 penetrates with 1L treatment, Opdivo will be able to share that portion. I believe that Keytruda can take a little more share of the Opdivo in the share of Keytruda, and I think Keytruda is taking a share in 2L treatments. Is this like a flaw or something when viewed simply in the quarter? Can you tell us a little more about the situation?

A : First of all, it is true that I-O/chemo is becoming popular in 1L treatment. However, there are still a certain number of patients who do not use I-O/chemo, and they are likely to receive 2L treatment. Now, many drugs that can be used in 2L treatment are intensively competing.

As for Opdivo, it is true that the number of prescriptions is on a declining trend at present.

Looking at the results by segment, Opdivo has a restriction in use for PD-L1 negative patients due to guidelines for optimal use promotion, for which other drugs are still slightly expanding. In this segment, we have not been able to take that part.

In addition, competition is intensifying for 1-49% of the PD-L1. In this area, we need to raise the volume of activities and work a little more.

However, at present, I haven’t heard from doctors that the direct sequence from I-O to I-O has been applied in the process. For patients who use I-O in their 1L treatment, there may be a case where an I-O re-challenge may be made for 3L or 4L treatment. However, at present, we have not been able to confirm the re-challenge of I-O in the 2L treatment.

Some information is not certain, so let me conclude the explanation here.

Q : Another question is about a new bispecific antibody. For phase 1, should this be understood as targeting healthy individuals?

A : For the first phase 1, we are targeting healthy individuals.

Q : I'm concerned about safety because it will suppress immune. In the first place, revitalization of PD-1 seems to amateurs like me that it will promote something into cancer.

So, what safety would be associated with any reaction to immune suppression? Is it a matter of concern, or do these antibodies have quite specific immune suppression?

A : Generally speaking, the state of immunity being abnormally active is autoimmune diseases. That state must be returned to normal, or In the case of cancer, immunity cannot recognize cancer, even though it should be able to recognize by its nature, which is unusual. We believe that returning this to normal is the effect through the PD-1.

In this sense, we hope we will be able to return to normal conditions by prescribing antagonist for cancer and agonist for autoimmune diseases.

On the other hand, with regard to safety, we believe it is necessary to deal with immunity while closely monitoring it.

Q : Is this related to Opdivo's PD-1 patent, or I should take this as another story, since the patent for this bispecific antibody has been obtained?

A : We are afraid that we can't comment on anything related to the patent.

Q : Please tell us about what was not on the pipeline's filing schedule in the future.

Another question is about a BRAF-inhibitor and a MEK-inhibitor. I believe that this was a success trial in Japan a while ago. Then, could you tell us about the filing schedule and the drug price if approval is successfully obtained?

The other question is about Karyopharm. They received approval in the US the other day. Do you think we can expect to be able to submit an application in Japan skipping phase 3? Can we expect the filing around the second half of this year or next year? What is your take on it? Please tell us.

A : With regard to BRAFTOVI and MEKTOVI, we plan to submit an application in the second half of FY2019 for BRAF mutant colorectal cancer.

Q : I've noticed that was included in the material. I'm sorry.

A : Drug prices are already set for melanoma, so it is expected that prices will be maintained at first. However, as the number of eligible drug will naturally expand significantly for additional indication, there is a possibility that a reduction in drug prices will occur in the future.

Anyway, we have to receive approval at first.

Q : How about Karyopharm?

A : I would like to refrain from discussing Karyopharm as this is related to the application, but basically, I think it is necessary to conduct a trial.

Q : In other words, in Japan, an application is filed including phase 3, which was a problem at AdCom. Am I right?

A : I think so.

Q : There was no BTK drug in the second quarter of Gilead the previous day, but today's company's materials are included. Can we interpret this as continuing to operate ongoing?

A : Overseas, as announced by Gilead, they have been discontinued for strategic reasons. Japan is operating as planned.

Q : Has the global rights been returned?

A : We plan to hold discussions with Gilead in the future.

Q : My question is about combination with CheckMate-227. Ultimately, what would be the long-term survival rate data? Can it narrow the gap between you and Keytruda or Tecentriq? In other words, this would be the key issue when you think about whether you can catch up and pass them. I also wonder when the five-year survival rate is likely to emerge. Can you tell us about the approach to the data about the combination?

A : The five-year survival rate takes a little more time. I have no answer to the question at this point.

Q : Naturally, it will only be applied for, so it will be packaged as a package.

A : That’s right.

Q : Also, I would like to hear about this. I think you can’t comment on this issue, but I dare to ask you, since a lot of discussions about the financial results have already been made. My question is about the lawsuit of Opdivo.

It was a bit written in media the last weekend, and it seems that Dr. Honjo will file a lawsuit. Could you update on this as much as possible? I have heard that your company certainly responded at the end of last month, but please tell us if you have any new information.

A : There is no new information in particular. Nothing in the Saturday's press release was from us, nor was it from Dr. Honjo. In response to questions from the media, his lawyer answered the questions, and accordingly, we have received a variety of inquiries. This doesn’t mean that there is any significant action.

Q : What about the situation in the United States? I believe that Bristol-Myers is on the front.

A : Do you mean Dana-Farber in the United States?

Q : Yes.

A : We have filed an appeal jointly with Bristol, Ono Pharmaceutical, and Dr. Honjo. I think that we will continue to monitor the situation in the future.

Q : I would like to reaffirm your performance. In the first quarter, sales increased by 2.7 billion yen and operating profit increased by 2.0 billion yen. As royalties have increased by 3.4 billion yen, what is the profitability of this business in areas other than royalties, especially long-term listed products and Opdivo?

A : Profitability other than Opdivo?

Q : Yes. There is a royalty of 20.8 billion yen, isn’t there?

A : Yes.

Q : Sales have increased by 2.7 billion yen since actual operating profit is almost 20.0 billion yen. As royalties have increased by 3.4 billion yen, what changes have been made in the profitability of long-term listed products and other products in areas other than so-called royalties?

A : There is no change. Nothing special is happening, so profitability is also not changing.

Q : In terms of the full-year period, the operating profit is expected to be 67.0 billion yen which means will increase by 5.0 billion yen compared to the previous fiscal year of 62.0 billion yen. In the first quarter, there is an increase of 2.0 billion yen in royalties compared to the previous fiscal year, but is this exactly as expected?

A : That's the case. In terms of royalties and other matters, we expect to achieve 88 billion this fiscal year.

Q : Merck is about 4.0 billion yen, Bristol's 15.4 billion yen, which is in line with expectations, compared to 88.0 billion yen.

A : Yes.